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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,749	01/22/2002	Christopher Meyer	3781-0102P	7350

2292 7590 10/27/2003

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,749	MEYER, CHRISTOPHER	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 18-33 is/are pending in the application.
- 4a) Of the above claim(s) 1, 19, 21, 23, 25, 27 and 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 22, 24, 28, 32 and 33 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8/22/03</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 1, 18-33 are pending. Claims 18, 20, 22, 24, 26, 28, 32, 33 are considered on the merits. Claims 1, 19, 21, 23, 25, 27, 29-31 are withdrawn from consideration as being drawn to a non-elected invention

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35U.S.C. 112. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 18, 28, 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation, "by binding to an enzyme involved in the conversion of ..." has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of this concept. There is only one exemplified inhibitor, which may be said to be a binder of ADP-glucose pyrophosphorylase and that is adenosine α -P-boranodiphosphoglucose. This is not sufficient support for the new genus, binder of enzyme involved in the conversion of α G-1-P to ADP glucose. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate

the possession of a concept after the fact. Thus, this insertion is considered to be the insertion of new matter for the above reasons.

Please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection over claim 18. However, removal of new matter may result in the reinstatement of the art rejection.

Indefinite

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 states that the inhibitor is an analogue of ADP-glucose. There is not definition in the specification that permits one of skill in the art to determine the metes and bounds of the term, analogue of ADP-glucose. How closely must an "analogue" correspond to ADP-glucose to be a member of the group? For example, would ADP-galactose be considered an analogue, would ATP-glucose be considered an analogue, etc..

Claim Rejections – 35 USC § 102

Claims 18, 20, 22, 24, 28, 32, 33 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dietzler *et al.* [U].

Claims 18, 20, 24 are directed to a one step method of identifying a compound capable of inhibiting the growth of a pathogenic microbe comprising: identifying a compound that inhibits the conversion of α -glucose-1-phosphate + ATP \rightarrow ADP-glucose and pyrophosphate (a reaction catalyzed by ADP glucose pyrophosphorylase).

Claim 22 is directed to a method of identifying a compound capable of inhibiting the growth of a pathogenic microbe comprising: incubating a sample of bacteria in the presence and absence of a test compound, assessing the effect on conversion of α -glucose-1-phosphate + ATP \rightarrow ADP-glucose and pyrophosphate wherein a lowered level of conversion in the presence of the test compound indicates that the test compound interferes with the activity of ADP glucose pyrophosphorylase (E.C. 2.7.7.27).

Dietzler *et al.* disclose a method comprising: incubating a sample of bacteria in media in the presence or absence of a compound as shown in Table 1, as assessing the effect of the activity of ADP-glucose synthetase (E.C. 2.7.7.27) in *E. coli*.

Also, on page 293, 6-azauracil is said to have been shown to be an inhibitor of ADP-glucose synthetase *in vitro*.

Declaration

The declaration submitted 8/22/03 has been carefully considered, but is not persuasive because: the method AS CLAIMED does not require the testing be performed in a pathogenic organism, merely that a compound be identified that inhibits the conversion of α glucose-1-P to ADP-glucose in pathogenic bacteria. A harmless bacteria could be used for this purpose because all bacteria share this pathway.

Response to Arguments

Applicant argues that Dietzler *et al.* do not teach a method of screening for inhibitors of ADPGPPase in pathogenic organisms. While this may be true, the one active step of the method "identifying a compound that inhibits the conversion of α G-1-P + ATP \rightarrow ADP glucose and PPi" or "incubating a sample of bacteria in a media in the presence or absence of a test compound..." is the

same as the step disclosed by Dietzler *et al.*. Thus, the one step method AS CLAIMED is anticipated.

Allowable Subject Matter

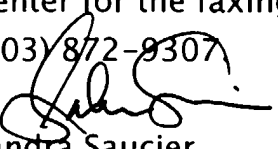
Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.


Sandra Saucier
Primary Examiner
Art Unit 1651
October 22, 2003